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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gregory L. Sundberg

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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

P.O. BOX 2938

MINNEAPOLIS, MN 55402

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/673,926	Applicant(s) SUNDBERG, GREGORY L.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 5, 6, 12, 15-18, and 21 are objected to because of the following informalities listed below. Appropriate correction is required.

In claim 5, “less than a diameter of the first portion of the fixation helix” is not clear as to whether the wire diameter of the helix is being discussed or the outside diameter of the entire helix is being discussed.

In claims 6 and 21, "1/3 to 1/2 of a diameter" is vague since it is not clear which diameter of the helix is being discussed.

In claim 12, the claim is not clear as to whether a method of making the lead is being claimed or an intermediate step since it is unclear what the diameter of the elements prior to coupling has to do with the final product.

In claim 15, “active...helix” is unclear as it does not provide for an electrically applied current/voltage being provided to the helix and the claim only provides that the helix is able to conduct electricity.

In claim 18, “via one or more recessed groove portions” is inferentially included and it is unclear whether applicant is functionally reciting them or positively reciting them.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 8-10, 19, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Peers-Travarton (4667686). Peers-Travarton shows housing, 12, piston, 40, helix coupled to piston (e.g. figure 2, 30), with a housing portion including a helical segmented guide, 32, that rides along the drive mechanism/helical drive grooves (e.g. figure 2, col. 4, lines 10-15), and includes a sleeve of radiopaque material coupled to the housing through the lead.

Claims 1, 2, 8, 14-16, 19, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachon (5531780). See, for example, figures 4-9 and corresponding description.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6, 11, 12, 13, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travarton in view of Bisping (4282885) (or for claims 3-6, 11-13, 17, 18, and 20-22 of Vachon in view of Bisping). Peers-Travarton or Vachon discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping teaches that it is known to put nearly the entire part of the fixation helix wire in a helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and 1/3 to 1/2 of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travarton or Vachon, the

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use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by Bisping since such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston, separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and/or extraction. In addition, for claim 12, the claim is a product by process limitation and does not add any further structural limitations to the final product of the helix coupled to the piston. In the alternative, it is well known when connecting two elements to make one diameter smaller than the other diameter to provide the predictable results of a more secure and tight fit of the two elements.

In the alternative for claims 6 and 21, Peers-Travaton or Vachon in view of Bisping discloses the claimed invention but does not disclose expressly $1/3$ to $1/2$ of the a diameter of the helix within the piston. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Peers-Travaton or Vachon in view of Bisping with $1/3$ to $1/2$ of the a diameter of the helix within the piston, because Applicant has not disclosed that $1/3$ to $1/2$ of the a diameter of the helix within the piston provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the wire completely in the recess as taught by Peers-Travaton or Vachon in view of Bisping, because it securely holds the wire during implantation.

Therefore, it would have been an obvious matter of design choice to modify Peers-Travaton or Vachon in view of Bisping to obtain the invention as specified in the claim(s).

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travaton. Peers-Travaton discloses the claimed invention except for the conductor electrically connected to the piston, piston electrically connected to the helix, and active helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable heart lead as taught by Peers-Travaton, with the conductor electrically connected to the piston, piston electrically connected to the helix, and active helix since it was known in the art that medical leads use a conductor electrically connected to the piston, piston electrically connected to the helix, and active helix to provide the predictable results of a helical fixation lead that actively directly stimulates cardiac tissue at the fixation site and allows for bipolar pacing and sensing.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travarton in view of Bisping (4282885). Peers-Travarton discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping teaches that it is known to put nearly the entire part of the fixation helix wire in a helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and 1/3 to 1/2 of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travarton, the use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by Bisping since such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston,

separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and extraction.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon. Vachon discloses the claimed invention except for the guide being a segmented helical guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Vachon, with the guide being a helical segmented guide since it was known in the art that implantable leads use a guide being a helical segmented guide to provide the predictable result of easily and smoothly advancing the helix from the lead.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fischer, Sr. is another example of a helical segmented guide.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
5/11/08